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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

Kenton L. Crowley, an individual, and John A. Flores, an individual

Plaintiffs,

v.

EpiCept Corporation, and DOES 1 through 20,

Defendants.

3:09-CV-00641-L-BGS

DEFENDANT EPICEPT CORPORATION'S MOTION TO PRECLUDE TESTIMONY AND EXPERT REPORT OF CHRIS PEDERSEN

Dept: 15, 5th Floor
JUDGE: HON. M. JAMES LORENZ

TRIAL DATE: MARCH 10, 2015

I. INTRODUCTION

Expert testimony must be the product of reliable principles and methods. The report and opinions offered by plaintiffs' expert, Chris Peterson, are not. Pedersen offers no support for his damages analysis, which relies upon key factual assumptions that lack any independent analysis and are opinions for which Pedersen lacks the requisite qualifications. Pedersen also offers improper legal conclusions. Because expert opinions must be grounded in more than the mere subjective belief and say so of the proponent, Pedersen's testimony fails to meet the reliability standard of Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) ("*Daubert I*"). As such, Pedersen should not be allowed to testify at trial and his report should not be admitted into evidence.

II. LEGAL STANDARD FOR ADMISSION OF EXPERT OPINION

A witness may offer opinion testimony where they are "qualified as an expert by knowledge, skill, experience, training, or education," and only if:

(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based upon sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; and

(d) the expert witness has reliably applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702; *see also Daubert I*; *Sterner v. U.S. Drug Enforcement Agency*, 467 F. Supp. 2d. 1017, 1033 (S.D. Cal. 2006) (recognizing that expert testimony is only admissible if it is "useful" and "reliable" to the trier of fact). When evaluating expert testimony, courts may consider:

(a) whether the theory or technique can and has been tested;

(b) whether the theory or technique has been subjected to peer review and publication;

(c) the known or potential rate of error for the technique; and

(d) the theory or technique's general degree of acceptance in the relevant scientific community.

Boyd v. City & Cnty. of San Francisco, 576 F.3d 938, 945 (9th Cir. 2009).

Courts are required to act in a "gatekeeping" role to ensure proper expertise, reliability, and relevance of expert testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999); *Daubert I,* 509 U.S. at 589-90. Before admitting expert testimony, the Court must decide if the expert will testify to "scientific, technical or other specialized knowledge" that will assist the trier of fact. *See* Fed. R. Evid. 702. This requires inquiry into the reliability of the expert's opinion. *See Daubert I,* 509 U.S. at 589-90; *Daubert v. Merrell Dow Pharms., Inc*., 43 F.3d 1311, 1316-17 (9th Cir. 1995) ("*Daubert II*"). Courts consider a variety of factors, including the reliability of the methods used to reach a conclusion and the manner in which the methods are applied. *Daubert I*, 509 U.S. at 592-93; *Daubert II*, 43 F.3d at 1316-17. In addition, the Court must examine whether the theory is reliably applied to the facts of the case. Fed. R. Evid. 702 (3); *see also Daubert I*, 509 U.S. at 591 (court must determine whether expert opinion is "sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute.") (quotation and citation omitted). If the analysis is not based upon relevant and reliable data, the expert's conclusion loses its reliability and should be excluded. *See General Elec. Co. v. Joiner*, 522 U.S. 136, 143-147 (1997) (excluding an expert's conclusion based on unreliable and irrelevant laboratory results); *see generally* Fed. R. Evid. 702 Advisory Committee Notes (2000 Amdmts).

The party offering expert opinion bears the burden of demonstrating, by a preponderance of the evidence, that the testimony satisfies these requirements. *See Daubert I*, 509 U.S. at 593, n.10; *Daubert II*, 43 F.3d at 1316. It is no remedy that the opposing party will have the opportunity to cross-examine the expert at trial and present rebuttal testimony. *See Lithuanian Commerce Corp., Ltd. v. Sara Lee Hosiery*, 179 F.R.D. 450, 458 (D.N.J. 1998) ("To conclude that evidence is

admissible because it is subject to such safeguard is, therefore, circular."). As explained below, admitting Pedersen's testimony would be severely prejudicial, given his lack of expertise and his failure to identify supporting evidence or data.

III. PEDERSEN'S OPINIONS EXPRESSED IN HIS REPORT

Pedersen's expert report containing four opinions. All four are improper subjects of expert testimony. In his report, Pedersen opinions on:

1. Whether EpiCepts efforts under the contract were "commercially and scientifically reasonable;
2. Whether EpiCept breached the contract;
3. Whether Plaintiffs sustained damages; and
4. Whether Plaintiffs could have mitigated their damages.

Declaration of Philip Tencer ("Tencer Dec."), Exhibit 1 (Pedersen Report, pp. 3-5). As discussed below, opinions 1, 2, and 4 are improper because they invade the province of the jury. Opinion 3 is improper as it is rests entirely on an assumption that the FDA would have approved plaintiffs' drug candidate,[1] which is speculative, conjectural and is not supported by any accepted scientific or economic analysis.

IV. PEDERSEN SHOULD NOT BE ALLOWED TO TESTIFY

A. Pedersen's Testimony Is Unreliable Because It Lacks Scientific or Economic Foundation and Is Not Supported by Facts or Data.

The unreliability of Pedersen's opinions are inherent in his report and further revealed by way of his deposition testimony, which confirms that his opinions are nothing more than a series of incomplete descriptions and unreasoned, unsupported assumptions that fail to acknowledge the difficulties in obtaining FDA approval of a drug candidate or the appropriate size of the relevant market for a drug infringing plaintiffs' patents. Pedersen opines in his report that, based upon the 20 year lifespan of patent:[2] 1) the market for NP-2 is $700,000,000 per year; 2) FDA

[1] EpiCept's internal nomenclature for plaintiffs' drug candidate is NP-2.

[2] Pedersen never bothers to address the fact that plaintiffs' '961 patent (which is the only relevant patent under the Assignment Agreement for the purposes of royalties) was filed on July 8, 1999 and the Assignment Agreement was entered on

approval and initial marketing and distribution infrastructure would take six years; 3) full market share would occur over the next four years; 4) which allows for ten years of commercial sales (Pedersen Report, p. 4). Pedersen provides no analysis to substantiate his opinions or test his assumptions; rather, he simply makes conclusions based upon cherry-picking various pieces of evidence in this case. *See* Pedersen Report, pp. 6-10, *compare* Tencer Dec., Exhibit B (Pedersen Depo., 148:1-149:23). For instance, he admittedly: 1) used a lay definition of "commercially and scientifically reasonable" for Opinion 1 (Pedersen Depo., 79:1-5); 2) has no experience or foundation to opine as to the FDA approval process to support Opinion 3 (*id*. at 13:2-15:13); and 3) has no independent data to support a $700,000 market for NP-2 (*id*. at 32:3-15, 141:15-17, 142:8-16). Pedersen actually testifies that the FDA would have approved NP-2 because it is "useful" and "valuable." (*id*. at 94:8-19). A lay person understands that the FDA's role is not tethered to the market value of a drug candidate, but instead focuses on the efficacy and safety of the drug candidate. Pedersen did not even explore these issues.

Pedersen's report and opinions fall far short of the reliability standard required by Rule 702 and *Daubert I*, and should therefore be stricken because he offers opinions despite admitting to having no relevant experience and relying almost exclusively upon personal witness interviews that are contrary to the witnesses' sworn testimony in this matter.

B. Pedersen's Testimony Is Unreliable Because It Is Based on His Subjective Beliefs, Not Scientific Principles or Verifiable Data.

Rule 702 precludes expert testimony based on "unsubstantiated speculation and subjective beliefs." *Diviero v. Uniroyal Goodrich Tire Co*., 114 F.3d 851, 853 (9th Cir. 1997). This turns, in part, on "whether the expert's theory can be

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December 1, 2000, which reduced the effective life of the patent to 18 years, 7 months. *See, e.g.,* 35 U.S.C. 154 (term of patent is 20 years from date of application); *see also* Assignment Agreement, p.1, §1.7 & §4.2 (identifying date Agreement was entered and identifying royalties based upon sales of "Patented Product" which is defined as a product that infringes the '961 patent).

challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability." Advisory Committee Notes to 2000 Amendments, Fed. R. Evid. 702. Expert opinions based on personal introspection rather than empirical analyses are commonly excluded by courts as being too speculative and conjectural to be of value. *See Martinez v. Davis*, 2011 WL 486255, at *1 (C.D. Cal. Feb. 4, 2011) (finding expert testimony based on "my opinion" and curriculum vitae inadmissible) (internal citations omitted); *see also Algarin v. New York City Dep't. of Correction*, 460 F. Supp. 2d 469, 477 (S.D.N.Y. 2006) (excluding expert whose report made clear that "his sole basis for alleging that these are the governing standards is a subjective inference he has drawn from his own personal experience" because it did not "equate to a methodology, let alone one generally accepted by the scientific community.")

Here, Pedersen relies upon subjective beliefs, rather than scientific principles, economic principles, or verifiable data. For example, Pedersen applies a discount rate of 23% to arrive at his damages opinion of $11 million. (Pedersen Report, p. 5). When questioned during his deposition why he chose a discount rate of 23%, as opposed to say, 18% or 30%, Pedersen testified that:

> I wanted it less than a venture capital rate because there's no obligation or responsibility to the royalty owner.... So it's not secured, like a secured annuity might get you, you know 8, 9 percent, or something like that. An unsecured one, you know, is going to be in the 15 to 20 percent range. So I kind of picked something between 20 and 25 percent to represent something – recognizing that it's an unsecured royalty, but acknowledging that the rate of return required would be less than that of the minimum for venture capital.

(Pedersen Depo., 245:11-246:5). Later, Pedersen testified he used the 23% discount rate because he thought that it "was a commensurate discount rate that would be required by an investor who would purchase the patent." (*Id.* at 261:4-10). This testimony confirms that the 23% discount rate has nothing to do with any empirical analysis. At best, it is based on his personal experience and, at worst, it is contrived from thin air. Either way, it is not proper for an expert opinion.

Similarly, Pedersen bases his opinion about the relevant market size by assuming that NP-2 would be sold "off label" and he does not undertake any analysis or have any understanding of how long it would take EpiCept or another company to acquire FDA approval for more than one indication of NP-2. (Pedersen Depo., 159:4-19). The facts he relied upon in assessing the potential market size for NP-2 are limited to statements by Peter Golikov, EpiCept's former president, concerning a comparable product, "the Endo patch," and plaintiffs' history treating patients with NP-2. (*Id*. at 102:4-103:7). At no time did Pedersen conduct any independent market research concerning a potential market for NP-2, and his reliance upon an inadmissible opinion from Mr. Golikov will not assist the jury.

Shockingly, Pedersen even goes so far as to opine that the FDA would have approved NP-2. In his deposition, Pedersen testified:

> Well, you're not going to have failed clinical trials. You already got ten years of use on it, years and years of it, beforehand. You're not going to have failure of clinical trials with this product. It's too valuable of a product. It cures people's pain where nothing else will do it. You're not going to have a failure of this product. There's absolutely no basis to come to the conclusion – none whatsoever – to come to the conclusion that there's any risk that the FDA would not have approved this product. Not one --- not one idea except some phantom concern they got over ketamine. They don't have concern over morphine patches. They don't have concerns over that, but they've got concern over ketamine stuff. It's ridiculous.
>
> Q: Is that your opinion?
>
> A. That's my opinion.

(Pedersen Depo., 94:5-25). The purported factual basis for this opinion is that Crowley and Flores had been using NP-2 on patients for years. On the other hand, he admits that he has never worked in drug development, he has no experience in getting a drug approved by the FDA, he has no experience dealing with the FDA, and he has no experience in clinical studies. (*Id*. at 13:2-15:13, 164:18-24).

The foregoing testimony makes it abundantly clear that Pedersen's opinions are not based upon sound scientific principles, economic principles or analysis, but

rather his own subjective conclusions and antidotal opinions of lay witnesses.

C. Pedersen Is Incompetent to Testify About FDA Approval, Safety or Efficacy of NP-2

Under Rule 702, an expert must be qualified by knowledge, skill, experience, training, or education to give an expert opinion. *Jinro Am., Inc. v. Secure Invs., Inc.*, 266 F.3d 993, 1004-07 (9th Cir. 2001). Testimony on subjects beyond the witness's expertise is properly excluded. *U.S. v. Chang*, 207 F.3d 1169, 1172-73 (9th Cir. 2000), *cert. denied*, 531 U.S. 860 (2000).

In addition to opining about how NP-2 was guaranteed FDA approval, Pedersen also takes it upon himself to opine that: 1) absorption of NP-2 was safe (Pedersen Depo., 56:17-57:25); and 2) NP-2 was effective (Pedersen Depo., 143:7-15; 155:11-22; 160:9-161:5-162:24). During his deposition, it was discovered that these opinions are based entirely upon plaintiffs informing Pedersen that NP-2 worked and that plaintiffs issued prescriptions of NP-2 to numerous patients over a 10 year period. (*Id*. at 94:5-25; 164:1-10). As such, these opinions meet none of the requirements for expert testimony.

As an initial matter, Pedersen makes no showing that he has the requisite knowledge, skill, experience, training, or education to give an expert opinion concerning drug toxicology or efficacy. *See Jinro Am., Inc*., 266 F.3d at 1004-07; Fed. R. Evid. 702(a); *see also Moore v. Ashland Chemical, Inc.,* 151 F.3d 269 (5th Cir. 1998) (en banc) (clinical doctor was properly precluded from testifying to the toxicological cause of the plaintiff's respiratory problem, where the opinion was not sufficiently grounded in scientific methodology). Pedersen's report is silent as to any relevant experience or expertise concerning these subject matters. He is not a medical doctor and he does not have any training or experience concerning drug safety or efficacy.

To the contrary, Pedersen claims to be qualified as an expert in business valuation matters (Pedersen Report, p. 11), who has a real estate license (*id*. at p.

12). He does not have a college degree. (Pedersen Depo., 7:22-8:13). Pedersen testified that he has never performed any toxicology or efficacy studies and has no personal experience with clinical studies or trials. (*Id. at* 13:16-23; 164:11-166:19). As such, Pedersen's proffered testimony on toxicology and efficacy is beyond his expertise and should be excluded. *Chang*, 207 F.3d at 1172-73.

Nor is Pedersen's testimony reliable. He has not undertaken any independent analysis, but instead relies upon opinions offered by plaintiffs, their attorney and Mr. Golikov[3] concerning the FDA approval timeline, likelihood of FDA approval, efficacy of NP-2 and the potential size of the market. (*See, e.g.*, Pedersen Depo., 32:3-34:1; 37:15-20; *see also* 38:19-39:16, 41:14-20 (testifying that he relied upon interviews of plaintiffs' patent attorney, Rob Phillips, for arriving at a value for the patents)). Even assuming he was otherwise qualified, Pedersen's failure to conduct any independent research or analysis necessarily means he cannot determine the reliability of the opinions upon which he relies. In short, Pedersen does nothing more than adopt selected snippets from witness interviews he conducted (but did not record) and documents produced in this case. Expert testimony parroting the opinions of others and lacking independent assessment is unreliable and should be excluded. *See Cholakyan v. Mercedes-Benz USA, LLC*, 281 F.R.D. 534, 544-47 (C.D. Cal. 2012). For these reasons, Pedersen should not be allowed to provide any opinions in this matter and his report should not be allowed into evidence.

D. Pedersen's Report Includes Improper Legal Conclusions.

[3] Pedersen purportedly relies upon interviews of Golikov. (Pedersen Depo., 30:17-3). However, Golikov, who was deposed before Pedersen issued his report, testified that it was hard to predict an FDA approval timeline because "every drug is different. Every drug has its own issues with the FDA. Ketamine has its own isssues and butambine has its own issues. So, its hard to speculate with the FDA." (Tencer Decl., Exhibit C, Golikov Depo., 153:20-154:1). He further testified that five years for FDA approval of NP-2 was "just a gestimate" that assumes "everything is going to go right, there's nothing funny with the FDA in terms of attitude with a certain kind of drug…. When [the FDA has] as attitude, you don't know how long its going to take to get approved. (*Id.* at 155:2-10). Golikov also testified that Crowley knew there were risks the FDA would not NP-2 due to concerns over ketamine and butamben. (*Id.* at 210:16-211:25). This sworn testimony contradicts Pedersen's purported interviews of Golikov.

Further, Pedersen improperly opines on ultimate issues, *i.e.* whether "EpiCept's efforts were commercially and scientifically reasonable," whether "EpiCept breached its contractual obligations" and "whether the inventors could have mitigated their damages." (Pedersen Report, pp. 3, 5). He further testified that it was his opinion that EpiCept never intended to develop NP-2. (Pedersen Depo., 62:22-63:4).[4] These are all improper legal conclusions that Pedersen should be precluded from testifying about at trial. Fed. R. Evid. 702; *see also Gable v. Nat'l Broadcasting Co.*, 727 F. Supp. 2d 815, 835-36 (C.D. Cal. 2010) ("It is well established that, an expert may not state his or her opinion as to legal standards, nor may he or she state legal conclusions drawn by applying the law to the facts."); *CFM Commc'ns, LLC v. Mitts Telecasting Co.*, 424 F. Supp. 2d 1229, 1233 (E.D. Cal. 2005) (excluding testimony of proposed expert as to the meaning and application of FCC regulations because "expert testimony consisting of legal conclusions is generally inappropriate") (internal quotations omitted).

E. Pedersen's Report Does Not Assist the Trier of Fact.

Moreover, expert testimony should be excluded where it does not assist the jury. *Beech Aircraft Corp. v. U.S.*, 51 F.3d 834, 842 (9th Cir. 1995) (noting that if expert testimony is offered to explain an issue or fact that jurors can understand on their own, it may be deemed non-helpful, and therefore inadmissible). Even where the factual context is technical, if the jury does not need assistance in understanding particular materials, expert testimony is not helpful or proper. *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1354 (Fed. Cir. 2007) (excluding, as unhelpful, a proffered expert's practice of merely quoting from the opposing party's materials and then drawing inferences therefrom). Pedersen's opinion concerning whether "EpiCept's efforts were commercially and scientifically reasonable are not helpful to the jury, given that he simply offers a lay conclusion: "No effort was made to develop the patent on a commercial basis. Correspondence

[4] This "opinion" is improper because Pedersen has no corporate motives expertise.

indicates that EpiCept never intended to develop the product commercially and that it was "intended as a back up, at best." (Pedersen Report, p. 3).

F. Pedersen's Report Relies on Speculation and Conjecture.

Finally, expert testimony that is speculation, guesswork, conjecture, and the like must be excluded. *Joy v. Bell Helicopter Textron, Inc.,* 999 F.2d 549, at 569 (D.C. Cir. 1993); *see also Tyger Constr. Co. v. Pensacola Constr. Co.,* 29 F.3d 137, 142 (4th Cir. 1994) ("An expert's opinion should be excluded when it is based on assumptions which are speculative and are not supported by the record.").

Pedersen offers two opinions that are completely speculative and conjectural. First, he opines that plaintiffs suffered damages because the FDA *would have* approved NP-2. He offers this opinion despite admitting he has no experience with the FDA approval process. (Pedersen Depo., 13:2-15:13). The uncontroverted facts are that an IND was never filed for NP-2 and it has never gone through a single human clinical trial to test safety or efficacy. An opinion based on assuming FDA approval, therefore, is inadmissible speculation and conjecture.

Second, Pedersen opines that the commercial market for NP-2 is $700,000,000 to "billions" per year. He bases that opinion exclusively on a witness statement and he has no idea if those figures are based on U.S. sales or international sales. (*Id*. at 32:3-15, 141:15-17, 142:8-16). The relevant market is critical, as plaintiffs were only entitled to royalties for U.S. sales. Again, Pedersen's testimony is not based on fact, analysis, or data, but simply contrived.

IV. CONCLUSION

For the foregoing reasons, EpiCept respectfully requests that Chris Pedersen be precluded from testifying at trial and that his report not be allowed into evidence.

Dated: March 5, 2015

TENCERSHERMAN LLP

By: /s/ Philip Tencer

Attorneys for Defendant
EpiCept Corporation

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I electronically filed the foregoing and the supporting declaration by Philip Tencer with clerk of Court using the CM/ECF system which will send a notice of electronic filing to those so identified, including the following:

Karen A. Larson,
Attorney for Plaintiffs
Kenton L. Crowley and John A. Flores

Dated: March 5, 2015

TENCERSHERMAN LLP

By: /s/ Philip Tencer

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